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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,524	06/26/2003	Tenny Chang	133	4831

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CARDICA, INC.
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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/607,524

Applicant(s)

CHANG ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 41-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 41-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 December 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 11/10/06; 12/13/06.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 13 December 2006.

The examiner acknowledges the changes made to the specification and the drawings and the amendments to the claims. The examiner also withdraws the objection to Claim 50, as it is unnecessary to use "the" or "said" in the context of introducing a new element, in this case a workpiece flap.

Claim Objections

1. Claim 1 objected to because of the following informalities: On line 8 of Claim 1 it reads "grasp vessel" and should be changed to --graft vessel-- or --grasped vessel--.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 8-11, 13-15, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Stefanchik et al., or **Stefanchik '019**, (U.S. Patent No. **6,187,019**) in view of Stefanchik et al., or **Stefanchik '700**, (U.S. Patent No. **6,036,700**).

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Claims 1 and 10: Stefanchik '019 discloses an anastomosis 60 tool configured to connect the graft vessel and the target vessel upon actuation and a transfer clamp 80 including two arms 84 and 82 to grasp the graft vessel, said transfer clamp configured to be attached to said anastomosis tool to place the graft vessel on said anastomosis tool, wherein at least one said arm comprises at least one element having an edge L, wherein the length of said edge is related to the anastomosis length (Figure 5).

Stefanchik '019 discloses the claimed device, except for the two arms being movable relative to one another, between an open position and a closed position, and the transfer clamp being detachable from said anastomosis tool before said actuation.

Stefanchik '700 teaches two arms 118 and 128 being movable relative to one another, between an open position and closed position being detachable (separate) from said anastomosis tool before said actuation (Figures 10-11). It would have been obvious to one of ordinary skill in the art at the time of invention to provide mutually relatively movable arms, movable between open and closed positions, as taught by Stefanchik '700, to Stefanchik '019 since it was known in the art that relatively movable arms achieve more flexibility for grasping and maneuvering around tissue and a detachable transfer clamp would provide more workspace for a small surgical site.

Claims 2-4: Stefanchik '019 discloses jaws, the jaws being the inner surfaces of 84 and 82, connected to said arm, fixed to said arm, and movable relative to the opposing arm (Figure 5, col. 6, lines 4-6).

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Claims 8-9: Stefanchik '019 discloses the one element being a portion of said arm and having a gripping surface defined thereon, wherein "gripping surface" is taken to mean a surface that can grip onto tissue (Figure 5).

Claim 11: Stefanchik '019 discloses the claimed device except for arms being biased to said closed position.

Stefanchik '700 teaches two arms **18** and **28** being biased to a closed position (col. 6, lines 30-34). It would have been obvious to one of ordinary skill in the art to provide arms being biased to a closed position, as taught by Stefanchik '700, to Stefanchik '019 since it was known in the art that clamping or grasping members that are biased or remain in a closed position, or grasping position, do not require an additional device or mechanism to hold the grasping member in a closed position.

Claim 13: Stefanchik '019 discloses a transfer clamp being configured to engage an anastomosis tool (Figure 5).

Claim 14: Stefanchik '019 discloses a transfer clamp including a stop **85** or **83** configured to contact an anastomosis tool (Figure 5).

Claim 15: Stefanchik '019 discloses a transfer clamp being configured to lock onto the anastomosis tool, wherein "lock" taken to mean "temporarily stop the motion of a mechanism" (Figure 5).

Claims 18-22: Stefanchik '019 discloses an extension arm **110** including a poke-through tip that is soft, substantially rigid, substantially tubular, and located at one end of the extension arm (Figure 12 and col. 7, lines 52-64).

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3. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No. **6,036,700**), as applied to Claim 1 above, and further in view of Vargas et al., or **Vargas '166** (U.S. Pub. No. **20020095166**).

Claims 5-7: Stefanchik '019 and Stefanchik '700 disclose the claimed device except for a cutting block movable and rotatable relative to the corresponding arms.

Vargas '166 teaches a cutting block **206a'-2** movable and rotatable relative to the corresponding arm **206a'** that prevents further cutting of the incision (Figure 10A and page 4, paragraph 56). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotatable cutting block relative to the corresponding arm, as taught by Vargas '166 to Stefanchik '019 and Stefanchik '700 in order to prevent further cutting of the incision.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No. **6,036,700**), as applied to Claim 11 above, and further in view of **Tartaglia** (U.S. Patent No. **4,318,313**).

Claim 12: Stefanchik '019 and Stefanchik '700 disclose the claimed device, including compression of the arms moving the arms from said closed position to an open position. (Stefanchik '700, Figures 10-11), except for finger pads being coupled to said arms, wherein compression of said finger pads move said arms from said closed position to said open position. It is noted that the finger pads themselves are not the cause of

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moving the arms from a closed position to an open position, but rather they are coupled to the arms that are compressed, moving the arms from a closed position to an open position.

Tartaglia teaches finger pads **20** and **20'** being coupled to arms **10** and **10'** which provides the user a larger surface area onto which they may place their fingers to prevent slippage, as well as ergonomic benefits (Figure 1 and col. 2, lines 4-8). It would have been obvious to one of ordinary skill in the art to provide finger pads coupled to the arms, as taught by Tartaglia, to Stefanchik '019 and Stefanchik '700, in order to provide the user with ergonomic benefits in using the device.

4. Claims 23-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No. **6,036,700**), as applied to Claim 18 above, and further in view of **Person** (U.S. Patent No. **6,200,263**).

Claims 23-27: Stefanchik '019 and Stefanchik '700 disclose the claimed device except for a retractor mount connectable to an extension arm, a holder being movable and rotatable relative to a remainder of the retractor mount, being connectable to said extension arm via said holder, and being configured to engage said anastomosis tool.

Person teaches a retractor mount **10** adapted to be connectable to an extension arm, a holder **30** being movable and rotatable relative to a remainder of the retractor

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mount, being adapted to be connectable to an extension arm via said holder, and being configured to engage an anastomosis tool (Figure 3 and col. 2, lines 29-46). Person teaches that a retractor mount with a holder provides greater versatility, is less invasive, and facilitates selective position adjustment of instruments relative to the retractor mount (col. 2, lines 2-5 and 14-18). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a rotatable holder connected to a retractor mount, as taught by Person, to Stefanchik '019 and Stefanchik '700, in order to provide greater versatility, to be less invasive, and to facilitate selective position adjustment of instruments.

5. Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Stefanchik '700**, (U.S. Patent No. **6,036,700**), as applied to Claim 1 above, and further in view of **Carranza et al.** (U.S. Patent No. **6,821,286**).

Claims 28-30: Stefanchik '019 and Stefanchik '700 disclose the claimed device except for a graft manipulator being movable relative to the transfer clamp, including two members spaced apart from and biased from one another, and a prong connected to the distal end of at least one said member.

Carranza et al. teaches a graft manipulator, such as forceps or tweezers, configured to be movable relative to a transfer clamp, including two members spaced apart from and biased from one another, and a prong connected to the distal end of at least one said member, wherein "prong" is taken to mean "projecting part," (col. 1, lines

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27-40). It would have been obvious to one of ordinary skill in the art to provide a graft manipulator, as taught by Carranza et al., to Stefanchik '019 and Stefanchik '700, since it was known in the art that a graft vessel must be manipulated by a mechanism that expands or spreads the end of a graft vessel so that it may be received by an anastomosis device without injuring the graft vessel.

6. Claims 41-42, 45, and 47-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) in view of **Wolf** (U.S. Patent No. **6,066,144**).

Claims 41 and 49-51: Stefanchik '019 discloses a transfer clamp, or a mechanism configured to register a graft vessel relative to a tissue effector, and adapted to be connectable to a tissue effector, the mechanism being configured to register at least one flap with at least one flap receiving surface and configured to be independent of said tissue effector during actuation thereof (see paragraph 2 above). Stefanchik '019 discloses the claimed device except for a tissue effector comprising an anvil and a staple holder movable relative to said anvil, as well as at least one flap located at an end of the graft vessel, wherein said staple holder includes at least one flap receiving surface, and wherein said mechanism is configured to register at least one said flap with at least one said flap receiving surface, and at least one spike extending from the at least one flap receiving surface.

Wolf teaches a tissue effector comprising an anvil **20** movable relative to staple holder, at least one flap located at an end of a graft vessel, wherein said staple holder

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includes at least one flap receiving surface which has at least one spike **112** extending from the at least one flap receiving surface (Figures 4, 8-9). Although the staple holder is not movable relative to the anvil in Wolf, it would have been obvious to one of ordinary skill in the art at the time of invention since it was known in the art that having the staple holder movable relative to the anvil enables the user to more control in managing the force being applied to the staples, and also it would have been obvious to provide a tissue effector which has at least one flap receiving surface with a spike, as taught by Wolf, to Stefanchik '019 in order to effectively support the thin wall of the coronary artery during attachment of staples or fastening devices.

Claim 42: Stefanchik '019 discloses a transfer clamp including at least one said arm, wherein at least one said arm comprises at least one element having an edge, wherein the length of the edge is related to anastomosis length (see paragraph 2 above).

Claim 45: Stefanchik '019 discloses a poke-through tip connected to said transfer clamp (see paragraph 2 above).

Claim 47: Stefanchik '019 discloses a transfer clamp being configured to register the graft vessel relative to said tissue effector (see paragraph 2 above).

Claim 48: Stefanchik '019 discloses a transfer clamp being configured to positively engage said tissue effector (see paragraph 2 above).

Claim 52: Stefanchik '019 discloses said mechanism being connectable to said tissue effector (see paragraph 2 above).

Claim 53: Stefanchik '019 discloses said mechanism being configured to positively engage said tissue effector (see paragraph 2 above).

14. Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Wolf** (U.S. Patent No. **6,066,144**), as applied to Claim 42 above, and further in view of **Vargas '166** (U.S. Pub. No. **20020095166**).

Claims 43 and 44: Stefanchik '019 and Wolf disclose the claimed device except for the one element being a cutting block, rotatable relative to the corresponding said arm.

Vargas '166 teaches one element being a cutting block, rotatable relative to a corresponding arm (see paragraph 3 above).

7. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Stefanchik '019** (U.S. Patent No. **6,187,019**) and **Wolf** (U.S. Patent No. **6,066,144**), as applied to Claim 41 above, and further in view of **Carranza et al.** (U.S. Patent No. **6,821,286**).

Claim 46: Stefanchik '019 and Vargas '353 disclose the claimed device except for a graft manipulator relative to said transfer clamp.

Carranza et al. teaches a graft manipulator movable relative to a transfer clamp (see paragraph 5 above).

Response to Arguments

8. Applicant's arguments filed 13 December 2006 have been fully considered but they are not persuasive.
9. Applicant argues that neither Stefanchik '019 nor Stefanchik '700 teach or suggest the limitation of having the transfer clamp configured to be attached to an anastomosis tool to place the grasp vessel on said anastomosis tool and detached from said anastomosis tool before actuation. The examiner disagrees. As maintained above, Stefanchik '700 provides the limitation in that it is essentially a transfer clamp that may be connectably detached to an anastomosis tool before before actuation of the device and that it would have been obvious to one of ordinary skill in the art at the time of invention to provide a detachable transfer clamp would since it would allow more workspace for a small surgical site.
10. Applicant's arguments with respect to Claims 41-53 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "M J Hayes", is positioned above the printed name.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER